Improvement of Delayed Gastric Emptying in Pylorus-Preserving Pancreaticoduodenectomy

Results of a Prospective, Randomized, Controlled Trial

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Objective: To determine if an antecolic or a retrocolic duodenojejunostomy during pylorus-preserving pancreaticoduodenectomy (PpPD) was associated with the least incidence of delayed gastric emptying (DGE), in a prospective, randomized, controlled trial.

Summary Background Data: The pathogenesis of DGE after PpPD has been speculated to be related to factors such as inflammation, ischemia, gastric atony, motilin levels, and type of surgical procedure. Previous retrospective studies have shown a lower incidence of DGE after antecolic duodenojejunostomy. A prospective trial is needed.

Methods: Forty patients were enrolled in this trial between May 2002 and April 2004. Just before duodenojejunostomy during PpPD, the patients were randomly assigned to undergo either an antecolic or a retrocolic duodenojejunostomy.

Results: DGE occurred in 5% of patients with the antecolic route for duodenojejunostomy versus 50% with the retrocolic route ($P = 0.0014$). Those with the antecolic route had a significantly shorter duration of postoperative nasogastric tube drainage than did those with the retrocolic route (4.2 days versus 18.9 days, respectively, $P = 0.047$). By postoperative day 14, all patients with the antecolic route could take solid foods, while only 55% (11 of 20) of the patients with the retrocolic route could take solid foods ($P = 0.0007$). The length of stay in the hospital was 28 days for the antecolic group versus 48 days for the retrocolic group ($P = 0.018$).

Conclusions: Antecolic reconstruction for duodenojejunostomy during PpPD decreases postoperative morbidity and length of hospital stay by decreasing DGE. Our data suggest that PpPD with antecolic duodenojejunostomy is a safer operation.

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Pylorus-preserving pancreaticoduodenectomy (PpPD) is an aggressive surgery involving pancreatic head resection for periampullary lesions. Persistent complications of PpPD have been reported and include pancreatic fistula, intra-abdominal abscess, intra-abdominal hemorrhage, and delayed gastric emptying (DGE).[1–4] Pancreatic fistula is associated with all of these postoperative complications and contributes to overall morbidity and mortality.[5–9]

DGE is not always associated with pancreatic anastomotic leak and has been a frustrating complication for which the mechanism has not been fully clarified. Although DGE is not life-threatening and can be treated conservatively, it results in discomfort and significant prolongation of the hospital stay that adds to hospital costs.[10–12] Therefore, DGE is an important complication and needs to be minimized in patients who have undergone PpPD.

The pathogenesis of DGE after PpPD has been speculated to include several factors such as local ischemia of the antrum,[13] the absence of duodenal motilin,[12,13] gastric atony caused by vagotomy,[14] and gastric dysrhythmias secondary to other complications like abscess.[15] Moreover, univariate analyses have indicated that other factors associated with DGE after PpPD could be the length of the preserved proximal portion of the duodenum, the volume of gastric juice, the duration of gastric tube placement, or administration of cisapride.[7]

Could the type of PD predispose to DGE, particularly if PpPD is used? With PpPD, 2 reconstruction routes are usually considered for duodenojejunostomy: the antecolic route or the retrocolic route. The incidence of DGE has been reported to be >30% for the retrocolic route,[12,16,17] compared with <15% for the antecolic route,[3,15] indicating that the antecolic route might be better. Only a randomized controlled trial could prove this hypothesis, thus the reason for our study.

PATIENTS AND METHODS

This randomized controlled trial was approved by the Ethical Committee on Clinical Investigation of Wakayama Medical University Hospital (WMUH). Patients were recruited into the study before surgery, on the basis of whether PpPD was anticipated, and appropriate informed consent was obtained. Between May 2002 and April 2004 at WMUH, 40 patients underwent PpPD for periampullary and bile duct

lesions. All 40 patients agreed to enroll in this study. They also agreed to follow-up at least 6 months after surgery. Specific exclusion criteria included peptic ulcer, tumor infiltration into the stomach, metastasis into lymph nodes of the prepylorus, and absence of informed consent.

Description of the Operations

At the time of PpPD, we removed the gallbladder, distal common bile duct, head of the pancreas, duodenum (except for the first portion), and 10 cm of the proximal jejunum. The proximal duodenum was carefully preserved to include 3 cm distal to the pylorus ring. The right gastric artery was divided along with the pyloric branch of the vagus nerve. In patients with malignant disease, the following areas of lymph nodes were removed: hepatoduodenal ligament, circumferentially around the common hepatic artery, and the right-half circumference of the superior mesenteric artery. This amount of lymph node dissection has been termed "D1α" by Kawarada and Isaji.[18]

Before the reconstruction, patients were randomized during the operation, by use of a computer-generated random number pattern, to 1 of the 2 reconstruction routes for duodenojejunostomy, the antecolic route or the retrocolic route (Fig. 1). As the first step in reconstruction during PpPD, the proximal jejunum was brought through the transverse mesocolon by the retrocolic route. Pancreaticojejunostomy was performed with duct-to-mucosal anastomosis in all patients. An inner mucosal anastomosis was performed between the pancreatic duct and the jejunal mucosa by use of 8 interrupted 5−0 PDS-II sutures (polydioxanone; Johnson & Johnson Co.), regardless of duct size. Knots of the anterior wall were outside the new lumen, and knots of the posterior wall were inside the lumen. Then the outer layer of the end-to-side pancreaticojejunostomy was constructed by use of 4−0 Vascufil suture (polybutester; Tyco Healthcare Co.) between the pancreatic tissue and the jejunal serosa to form a seromuscular envelope. The new lumen was intubated with a 5-Fr polyethylene pancreatic drainage tube with a small knob (Sumitomo Bakelite Co.) and exteriorized through the jejunal limb. A one-layer choledochojejunostomy was constructed using interrupted 5−0 PDS-II without a stent.
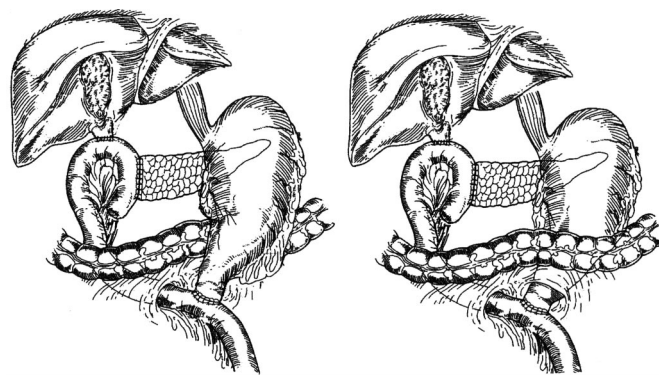

FIGURE 1. Reconstruction routes for the duodenojejunostomy after pylorus-preserving pancreaticoduodenectomy. Left, Antecolic route. Right, Retrocolic route.

The final step was construction of the duodenojejunostomy using a 2-layered anastomosis. The inner layer was 4−0 PDS-II and the outer layer used 3−0 silk for seromuscular anastomosis. As above, reconstruction by the antecolic or retrocolic route was chosen by random selection (Fig. 1). Two closed-suction drains were placed in the right upper quadrant, around the pancreatic and biliary anastomosis. A 16-Fr nasogastric tube was then inserted.

For postoperative management, an intravenous H2 blocker was administered to all patients. None of the patients was given proton pump inhibitors, somatostatin analogues, or prokinetic agents such as erythromycin.

Data Collection

Data were collected prospectively for all patients and included history, pathologic examination, postoperative clinical information, and complications. The time for removal of the nasogastric tube was determined when drainage was <500 mL/day.

Study Endpoints

DGE was defined as 1) prolonged aspiration of >500 mL/day from a nasogastric tube left in place for ≥10 days (DGE10),[19−23] 2) need for reinsertion of a nasogastric tube,[21] or 3) failure of unlimited oral intake by the 14th POD (DGE14).[19,20] Percentage of oral intake of solid foods was defined as the ratio between actual intake and provided diet.

The secondary endpoints were mortality and morbidity, including pancreatic fistula, intra-abdominal hemorrhage, and intra-abdominal abscess. A pancreatic fistula was defined as drainage of >50 mL/day of fluid from the external drains that contained an amylase that was >3-fold higher than the upper limit of normal for serum amylase (>459 IU/L) on or after 1st POD. Intra-abdominal abscess was defined as any fluid detected by computed tomography or ultrasound sonography that required drainage.

Statistical Analyses

The study design to predict the number of patients necessary for statistical validity (2-sided) was based on the premise of improving the DGE rate from 30% to 10%, with the α set at 0.05 and the β set at 0.2, yielding a power of 80%. We calculated that 58 patients were required in each arm of this study, for a total study population of 116 patients. Statistical evaluation was carried out by use of the 2-tailed χ^2 test, Fisher exact test, and the Student t test. Results were reported as mean ± SD. Significance was defined as $P < 0.05$. An interim analysis using Bonferroni's method was planned to be calculated with 20 patients per arm. At this interim analysis, the DGE rate in the antecolic (ANTE) group was significantly lower than the retrocolic (RETRO) group. These data indicated a clear benefit with reconstruction by the antecolic route, and, after careful evaluation of these data, we decided ad to terminate the study, owing to statistical and moral factors.

RESULTS

The 40 enrolled patients received their PpPD for the reasons listed in Table 1, and there was no difference in

TABLE 1. Patient Characteristics

| Characteristic | Reconstruction of Duodenojejunostomy | | |
	Antecolic Route (n = 20)	Retrocolic Route (n = 20)	P
Age (yr)*	63.1 ± 9.21	66.7 ± 12.2	0.239
Male/female	11/9	10/10	0.752
Disease			NS
Malignant/benign	16/4	16/4	
Pancreatic cancer	4	10	
Bile duct cancer	10	2	
Ampullary cancer	2	4	
IPMN	2	3	
Solid-pseudopapillary tumor	1	0	
Pancreatitis	1	1	
Blood loss (mL)*	1087 ± 794	1285 ± 1915	NS
Blood replacement (units)*	2.1 ± 2.8	2.1 ± 3.9	NS
Operation time (min)*	379 ± 77	351 ± 61	NS

NS indicates not significant; IPMN, intraductal papillary mucinous neoplasms.
*Data are mean ± SD.

background with regard to age, gender, disease, or ratio of malignant disease to benign disease between 2 groups. Comparison of the antecolic and retrocolic duodenojejunostomy reconstruction groups showed no difference in regard to age, gender, disease, or ratio of malignant disease to benign disease.

The overall incidence of DGE was 27.5% (11 of 40 patients). The incidence of DGE was 5% (1 of 20 patients) in ANTE group, compared with 50% (10 of 20 patients) in the RETRO group (*P* = 0.0014). The differences between the 2 groups in management of the nasogastric tube, toleration of

TABLE 2. Delayed Gastric Emptying (DGE) and Hospital Stay

	Antecolic Route (n = 20)	Retrocolic Route (n = 20)	P
Patients with DGE (no. [%])	1 (5)	10 (50)	0.0014
Postoperative nasogastric tube (days)*	4.2 ± 4.0	18.9 ± 36.0	0.047
Maximum nasogastric tube residual (mL)*†	389 ± 505	800 ± 564	0.017
Solid foods begun (days)*	8.1 ± 1.6	19.7 ± 34.3	NS
Solid foods begun at 14th POD	20/20	9/19	0.0007
Percentage of solid foods at 14th POD*	52.5 ± 20.2	27.1 ± 27.3	0.0025
Length of postoperative hospital stay (days)*	28.7 ± 5.7	47.7 ± 37.7	0.018

NS indicates not significant; POD, postoperative day.
*Data are mean ± SD.
†Maximum drainage of gastric juice per day.

solid foods, and postoperative length of stay are listed in Table 2.

As listed in Table 3 there were no differences between groups for other postoperative complications; specifically, there was no major leakage of the pancreaticojejunostomy or intra-abdominal hemorrhage. The 1 patient with pancreatic fistula required percutaneous interventional drainage, resulting in a complete cure. Each group had one case of choledochojejunostomy leak, and they were both treated with percutaneous interventional drainage for cure. One case of gastrointestinal hemorrhage that occurred in the RETRO group was due to a Dieulafoy's-type gastric ulcer with active bleeding, resulting in death by acute hemorrhagic shock. Another gastrointestinal hemorrhage occurred in the RETRO group; however, in this patient, endoscopic examination was negative and the hemorrhage stopped spontaneously. The single case of adult respiratory distress syndrome was in the RETRO group and required the use of a respirator and admission of the patient to the intensive care unit.

DISCUSSION

Surgery to remove the pancreatic head used to be associated with a significant risk for mortality from complications such as pancreatic fistula; however, resection was the only treatment that offered long-term survival for patients with malignant tumors of the pancreatic head.[5,24–26] PpPD has become popular since the report of Traverso and Longmire was published in 1978.[27] As the mortality rate has fallen with the modern experience of high-volume centers, the most common postoperative complications for pancreatic head resection remain pancreatic fistula, infection, and DGE.[1,7]

DGE after PpPD is thought to be caused by prolonged gastroparesis during the first 2 to 4 postoperative weeks.[1] A few studies have shown that PpPD had a higher incidence of DGE versus the standard pancreaticoduodenectomy (PD). At the same time, other studies have observed no difference in the incidence of DGE after PpPD or PD.[23–25] Regardless of

TABLE 3. Postoperative Complications

Complication	Antecolic Route (n = 20)	Retrocolic Route (n = 20)	P
Major leakage of pancreaticojejunostomy	0 (0)	0 (0)	NS
Pancreatic fistula	1 (5)	0 (0)	NS
Intra-abdominal hemorrhage	0 (0)	0 (0)	NS
Gastrointestinal hemorrhage	0 (0)	2 (10)	NS
Intra-abdominal abscess	1 (5)	4 (20)	NS
Bile leakage of choledochojejunostomy	0 (0)	1 (5)	NS
Leakage of gastrojejunostomy	0 (0)	0 (0)	NS
Acute pancreatitis	0 (0)	0 (0)	NS
Wound infection	1 (5)	1 (5)	NS
Reoperation	0 (0)	1 (5)	NS
Adult respiratory distress syndrome	0 (0)	1 (5)	NS
Admission to intensive care unit	0 (0)	1 (5)	NS
Mortality	0 (0)	1 (5)	NS

NS indicates not significant.
Data are no. (%) of patients.

the type of PD, DGE has been reported to occur in 9% to 37% of patients.[4,23,24] Recently, the incidence of DGE (730 cases) was reviewed in the literature. The average incidence of DGE10 was found to be 13.9%.[28] The occurrence of DGE requires the prolonged use of nasogastric intubation and may require the initiation of parenteral or enteral nutritional support. Ultimately, DGE delays hospital discharge. The incidence of DGE needs to be decreased. There is clearly a difference in delivery of postoperative care between Japan and the United States. The duration of nasogastric drainage, the delay in reinstituting diet, and the length of hospital stays are significantly different. The nasogastric tube is removed on the first POD at major healthcare centers in the United States and Europe where a high volume of PDs are performed,[15,29,30] which is the difference in the Japanese management.

DGE has been thought to be caused by local ischemia of the antrum, the absence of duodenal hormones, inflammation from pancreaticoenterostomy, edema from duodenojejunostomy, and gastric atony caused by vagotomy. Moreover, reported results of univariate analysis have suggested that factors associated with DGE after PpPD are the length of the preserved proximal portion of the duodenum, volume of gastric juice, duration of gastric tube placement, and administration of cisapride.[7] However, the true mechanism of DGE is still unclear, and its pathophysiology has not been elucidated.

There have been a few reports suggesting that DGE rates may vary with how the gastrointestinal tract is routed out of the stomach.[11,19] In a retrospective study, Park et al[11] reported that the incidence of DGE associated with the retrocolic route of duodenojejunostomy was 31.7%, compared with 6.5% for the antecolic route. Similar findings were described by and Horstmann et al.[15] However, no randomized, prospective study has been done comparing reconstruction routes for duodenojejunostomy and DGE.

In the present study, the total incidence of DGE was 27.5% among patients who had undergone PpPD, which is within the range reported by others but on the higher side. Perhaps this higher incidence is fertile ground to study methods to minimize DGE. We observed a 50% incidence of DGE in RETRO group and only a 5% incidence in the ANTE group. Moreover, patients in the RETRO group demonstrated longer duration of nasogastric tube use, less ability to eat solid foods, and longer duration of postoperative hospital stay.

Why was there such a difference in the incidence of DGE between these groups? We can only speculate about the low number of cases in each group. In both groups, careful bowel, vascular, and selective vagal transections were accomplished to maintain duodenal mucosal color and the same level of selective vagotomy. Pancreatic fistula is one complication associated with DGE after PpPD.[26,31] However, our incidence of pancreatic fistula was only 2.5%. In the RETRO group with frequent DGE, we did not observe many other complications, conflicting with the results of several reports where most cases of DGE are associated with other complications.[15,32] Although the incidence of other major complication in Table 3 was not significantly higher, perhaps the slightly higher incidence of hemorrhage or abscess in the RETRO group contributed to some risk for DGE. A weakness

of our study is the low numbers in each group because of our decision to terminate the study after the first interim analysis showed a marked difference in DGE. We are therefore unable to perform subset analyses.

The average incidence of DGE after PD in the literature has been reported to be 13.9%.[28] The 50% incidence of DGE in the RETRO group of the present study is comparable with the reported incidence of 33% after PpPD when retrocolic reconstruction was done and pancreatic juice was not allowed to enter the intestine (the pancreatic tube was exteriorized).[32] Exteriorizing pancreatic juice markedly increases gastric secretion and deteriorates gastric motor activity,[33] owing to higher acid output due to the elevation of serum gastrin level.[34,35] A situation predisposing to DGE could result when the newly created environment of duodenojejunostomy is exposed to increased gastric volume (due to external pancreatic juice drainage). We can only speculate that more resistance to the increased gastric volume was present in the RETRO group versus the ANTE group. Our technique of using an external pancreatic drain may be a fortuitous as a good experimental model to study DGE. The reader should be cautioned to consider the influence of external pancreatic tubes on gastric secretion when analyzing the literature of DGE and PpPD.

CONCLUSION

We conclude that this prospective, randomized, controlled trial supports the concept that an antecolic duodenojejunostomy may improve the outcomes of PpPD due to less DGE and a shorter hospital stay.

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